

Complete Summary

GUIDELINE TITLE

Antenatal corticosteroids revisited: repeat courses.

BIBLIOGRAPHIC SOURCE(S)

Antenatal corticosteroids revisited: repeat courses. NIH Consens Statement Online 2000 Aug 17-18; 17(2):1-10.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Preterm delivery

GUIDELINE CATEGORY

Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Nurses

Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To review the evidence on benefits and risks of repeat courses of antenatal corticosteroids
- To develop consensus recommendations
- To determine what additional research should be conducted in this area

TARGET POPULATION

Pregnant women between 24 and 34 weeks gestation who are at risk of preterm labor

INTERVENTIONS AND PRACTICES CONSIDERED

Repeat courses of antenatal corticosteroids with betamethasone or dexamethasone delivered either weekly, occasionally, or as rescue therapy (e.g., single-course steroids given on an as-needed basis for planned or imminent delivery).

MAJOR OUTCOMES CONSIDERED

Benefits and risks of repeat courses of antenatal corticosteroids

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The literature was searched through electronic databases including MEDLINE (National Library of Medicine [NLM]), and an extensive bibliography of references was provided to the panel and the conference audience.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Scientific evidence was given precedence over clinical anecdotal experience.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Consensus Development Conference)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The National Institutes of Health (NIH) Consensus Development Panel, answering predefined questions, developed their conclusions based on the scientific evidence presented in open forum and the scientific literature. The panel composed a draft statement that was read in its entirety and circulated to the experts and the audience for comment. Thereafter, the panel resolved conflicting recommendations and released a revised statement at the end of the conference.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The National Institutes of Health (NIH) Consensus Development Panel on Antenatal Corticosteroids Revisited: Repeat Courses finalized the revisions within a few weeks after the conference. The draft statement was made available on the World Wide Web immediately following its release at the conference and was updated with the panel's final revisions.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Excerpted by the National Guideline Clearinghouse (NGC):

Clinical Recommendations

- All pregnant women between 24 and 34 weeks gestation who are at risk of preterm delivery within 7 days should be considered candidates for antenatal treatment with a single course of corticosteroids.
- Treatment consists of two doses of 12 mg of betamethasone given intramuscularly 24 hours apart or four doses of 6 mg of dexamethasone given intramuscularly 12 hours apart, as recommended by the consensus panel in 1994. There is no proof of efficacy for any other regimen.
- Because of insufficient scientific data from randomized clinical trials regarding efficacy and safety, repeat courses of corticosteroids should not be used routinely. In general, it should be reserved for patients enrolled in randomized controlled trials. Several randomized trials are in progress.

Conclusions

- The collective international data continue to support unequivocally the use and efficacy of a single course of antenatal corticosteroids using the dosage and interval of administration specified in the 1994 Consensus Development Conference report.
- The current benefit and risk data are insufficient to support routine use of repeat or rescue courses of antenatal corticosteroids in clinical practice.
- Clinical trials are in progress to assess potential benefits and risks of various regimens of repeat courses. Until data establish a favorable benefit-to-risk ratio, repeat courses of antenatal corticosteroids, including rescue therapy, should be reserved for patients enrolled in clinical trials.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The panel, answering predefined questions, developed their conclusions based on a comprehensive review of scientific evidence presented in open forum. Scientific evidence was given precedence over clinical anecdotal experience.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

While the data on possible benefits of repeat or rescue courses of corticosteroids are limited in quality, some studies suggest possible benefits in reduction of the incidence and severity of respiratory distress syndrome, and reduction in the incidence of patent ductus arteriosus. There is little or no evidence to support other possible benefits, including a reduction in mortality rate or reductions in the

incidence of intraventricular hemorrhage, chronic lung disease, sepsis, necrotizing enterocolitis, or retinopathy of prematurity.

POTENTIAL HARMS

Evidence on the short- and long-term adverse effects of repeat doses of corticosteroids is contradictory and therefore inconclusive, however, some studies suggest increased maternal infection and suppression of the maternal hypothalamic-pituitary-adrenal axis. Fetal/neonatal effects include decreased somatic and brain growth, adrenal suppression, neonatal sepsis, chronic lung disease, and mortality. Although no increase in the incidence of cerebral palsy was noted, neurodevelopmental follow-up studies suggest an increase in psychomotor delay and behavioral problems.

QUALIFYING STATEMENTS

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This statement is an independent report of the panel and is not a policy statement of the National Institutes of Health (NIH) or the Federal Government.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Antenatal corticosteroids revisited: repeat courses. NIH Consens Statement Online 2000 Aug 17-18; 17(2):1-10.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 Aug 18

GUIDELINE DEVELOPER(S)

National Institute of Child Health and Human Development - Federal Government Agency [U.S.]
National Institutes of Health (NIH) Consensus Development Panel on Antenatal Corticosteroids - Independent Expert Panel

GUIDELINE DEVELOPER COMMENT

National Institutes of Health (NIH) Consensus Statements are prepared by a non-advocate, non-Federal panel of experts, based on (1) presentations by investigators working in areas relevant to the consensus questions during a 2-day public session; (2) questions and statements from conference attendees during open discussion periods that are part of the public session; and (3) closed deliberations by the panel during the remainder of the second day and morning of the third. This statement is an independent report of the panel and is not a policy statement of the National Institutes of Health (NIH) or the Federal Government.

The primary sponsors of this meeting were the National Institute of Child Health and Human Development and the National Institutes of Health (NIH) Office of Medical Applications of Research. The National Institute of Nursing Research and the National Heart, Lung, and Blood Institute were co-sponsors.

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

National Institutes of Health (NIH) Consensus Development Panel on Antenatal Corticosteroids Revisited: Repeat Courses

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Larry C. Gilstrap III, MD (Panel and Conference Chairperson); William H. Clewell, MD; Mary E. D'Alton, MD; Marilyn B. Escobedo, MD; Joel Frader, MD; Dwenda K. Gjerdingen, MD; Jan Goddard-Finegold, MD; Robert L. Goldenberg, MD; Maureen Hack, MBChB; Thomas N. Hansen, MD; Ralph E. Kauffman, MD; Emmett B. Keeler, PhD; William Oh, MD; E. Albert Reece, MD; Elizabeth J. Susman, PhD, RN; Marilyn G. Vogel, EdD.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All of the panelists who participated in the National Institutes of Health (NIH) conference and contributed to the writing of this consensus statement were identified as having no financial or scientific conflict of interest, and all signed conflict of interest forms attesting to this fact.

ENDORSER(S)

National Heart, Lung, and Blood Institute (U.S.) - Federal Government Agency [U.S.]

National Institute for Nursing Research - Federal Government Agency [U.S.]

GUIDELINE STATUS

This is the current release of the guideline. It updates/supplements the 1994 Consensus Statement titled "The Effect of Corticosteroids for Fetal Maturation on Perinatal Outcomes."

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Available from the [NIH Consensus Development Conference Program Web site](#). Also available from the [National Library of Medicine Health Services/Technology Assessment Text \(HSTAT\) Web site](#).

Print copies: Available from the NIH Consensus Development Program Information Center, PO Box 2577, Kensington, MD 20891; Toll free phone (in U.S.), 1-888-NIH-CONSENSUS.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- A program/abstract book is available from the [NIH Consensus Development Conference Program Web site](#).

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on May 23, 2001. The information was verified by the guideline developer as of October 23, 2001.

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